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| 10/519,387 | 12/27/2004 | Zeev Maor | 1268-170U | 6945 |
| 23429 7590 04/10/2009 LOWE HAUPTMAN HAM & BERNER, LLP 1700 DIAGONAL ROAD SUITE 300 ALEXANDRIA, VA 22314 | | | EXAMINER FRAZIER, BARBARA S | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,387

Applicant(s)

MAOR ET AL.

Examiner

BARBARA FRAZIER

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6,8,11,12,16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,8,11,12,16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/22/09 has been entered.

Status of Claims

2. Claims 1, 3, 5, 6, 8, 11, 12, 16, and 17 are pending in this application. Cancellation of claims 2, 4, 7, 9, and 13-15 is acknowledged. Claim 10 stands canceled. Addition of new claims 16 and 17 is acknowledged.
3. Claims 1, 3, 5, 6, 8, 11, 12, 16, and 17 are examined.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Claims 1, 3, 5, 6, 8, 11, 12, 16, and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The

claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1, as amended, and new claim 17, now recites the limitation, "said demagnetized nanoparticles being present in a quantity greater than naturally found in Dead Sea mud" (lines 5-6 of claim 1 and lines 2-4 of claim 17). Applicants assert that the quantity of particles used in the preparation is exemplified in the application to be 1% and above, citing Examples 3-12. However, Examples 3-12 teach that the magnetic hard compositions of amounts of 1% and above are selected from magnetite, Dead Sea bath salt, Dead Sea minerals, Dead Sea Mud, or a mixture thereof. It is not clear from this description that the amount of demagnetized nanoparticles are necessarily present in a quantity greater than that naturally found in Dead Sea mud, because neither magnetite nor Dead Sea mud are required components in any of the Examples, and the amounts of magnetite relative to Dead Sea mud are not specified. Therefore, the limitation "said demagnetized nanoparticles being present in a quantity greater than naturally found in Dead Sea mud" constitutes new matter.

Additionally, new claim 16 recites the limitation, "said demagnetized nanoparticles being in a quantity greater than 400 ppm". Applicants assert that support for "quantity greater than 400 ppm" can be found in Table 4 which specifies the content of strontium (Sr) naturally found in the Dead Sea mud to be 400 ppm (page 6 of specification). However, since it is not clear from the disclosure that the amount of demagnetized nanoparticles are necessarily present in a quantity greater than that

naturally found in Dead Sea mud, for reasons stated above, it is not clear that the amount of strontium hexaferrite is necessarily greater than 400 ppm. Therefore, the limitation "said demagnetized nanoparticles being in a quantity greater than 400 ppm" constitutes new matter.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **Claims 1, 3, 5, 6, 8, 11, 12, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 1, as amended, is now drawn to a cosmetic preparation comprising demagnetized nanoparticles dispersed therein (line 3), said demagnetized particles being suitable for magnetization when dispersed in said preparation or when applied to the skin of the subject (lines 6-8). The claim reads that the particles are both demagnetized and suitable for magnetization when dispersed in said preparation. It is not clear if the particles exist in both a demagnetized and magnetized state when dispersed in the preparation.

Additionally, it is not clear what is meant by the phrase "said demagnetized nanoparticles being present in a quantity greater than naturally found in Dead Sea mud". While certain elements in magnetic particles, such as strontium, are also found in Dead Sea mud, there is no evidence that the magnetic particles themselves, such as those listed at page 7, lines 1-7 of Applicant's specification, are "naturally found" in Dead Sea

mud, as evidenced by Applicant's analysis of Dead Sea mud in Tables 1-4 (see pages 5 and 6 of Applicant's specification).

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
9. **Claims 1, 3, 5, 6, 8, 11, 12, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maor (WO 00/40255) in view of Zastrow et al (US Patent 5,961,988, hereinafter "Zastrow '988"), and further in view of Shiga Yoko (JP 4,108,710, abstract submitted herewith).**

The claimed invention is drawn to a cosmetic preparation for topical application onto skin of a subject, said preparation comprising Dead Sea mud and demagnetized nanoparticles dispersed therein, said demagnetized nanoparticles being present in a quantity greater than naturally found in Dead Sea mud, said demagnetized nanoparticles being suitable for magnetization when dispersed in said preparation or when applied to the skin of the subject.

Maor et al teach a pharmaceutical cream composition for topical application for the treatment of skin disorders and skin diseases, comprising Dead Sea Mud as an active ingredient (abstract), which contains Dead Sea minerals (pages 4 and 5) and evidenced by Applicant's specification (see page 6 of Applicant's disclosure).

Comment [11]: now cancelled

Maor et al do not teach the presences of demagnetized nanoparticles.

Zastrow '988 teach a dermatological preparation containing magnetically hard particles such as strontium hexaferrite (col. 1, lines 37-39) which may be used in an emulsion/cream (for example, see col. 3, lines 23-24, Example 1C, and Example 2). It is noted that said particles are the same as those exemplified by Applicants; see page 7, lines 1-7 and claims 16-17 of Applicant's disclosure. The magnetic particles have a particle size in the range of 80 to 550 nm (col. 1, lines 41-42), and thus are "nanoparticles". The magnetic particles have a high wound healing effect and anti-inflammatory effect (col. 1, lines 22-23) and are useful for hypersensitive skin (Example 2).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to combine the magnetic particles taught by Zastrow '988 with the Dead Sea mud cream taught by Maor et al; thus arriving at the claimed invention. One skilled in the art would have been motivated to add the magnetic particles taught by Zastrow et al to the Dead Sea mud cream taught by Maor et al, because the addition of the magnetic particles provides the benefits of high wound healing effect and anti-inflammatory effect, as well as treatment of hypersensitive skin, as taught by Zastrow '988. One would reasonably expect success from the combination of the of the Dead Sea mud cream taught by Maor et al with the magnetic particles taught by Zastrow '988, because both references are drawn to cosmetic compositions in the form of emulsion/creams for the treatment of skin disorders.

Regarding the limitation that the nanoparticles are demagnetized when dispersed in the preparation but suitable for magnetization when dispersed in the preparation or

when applied to the skin, Zastrow '988 is silent with respect to when the nanoparticles are magnetized.

Shiga Yoko teach preparations for stimulating blood circulation comprising magnetic particles, such as ferromagnetic particles (abstract). Shiga Yoko further teach that, when ferromagnetic substances are dispersed in a cosmetic preparation in the demagnetized state and the preparation is magnetized after cosmetic application to the skin, this form of application is said to have a circulation-stimulating effect (see abstract).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use demagnetized magnetic particles which are magnetized after cosmetic application to the skin in the composition of Maor and Zastrow '988; thus arriving at the claimed invention. One skilled in the art would be motivated to do so because the use of the magnetic particles of Zastrow '988 in the form as taught by Shiga Yoko results in the benefit of increased circulation to the skin, as taught by Shiga Yoko. One would reasonably success from the use of the magnetic particles of Zastrow '988 in the form taught by Shiga Yoko because both references are drawn to the use of ferromagnetic particles for cosmetic application to the skin.

Regarding the limitation that the demagnetized nanoparticles are present in a quantity greater than naturally found in Dead Sea mud, Maor teaches that the amount of Dead Sea Mud is 1-6 wt% (abstract), and Zastrow '988 teach that the amount of particles is 0.001 to 50 wt% (col. 1, lines 62-63). Based on said amounts, the range of amounts Maor and Zastrow '988 overlap with the amount range of the claimed invention

wherein the demagnetized nanoparticles are present in a quantity greater than naturally found in Dead Sea mud. One skilled in the art would be able to manipulate the amounts of Dead Sea mud and particles to amounts from within said ranges by routine experimentation, in order to optimize the efficacy of the resultant composition.

Regarding claim 3, Applicants have elected strontium hexaferrite as the elected species for the nanomagnetic particles. Zastrow '988 teach strontium hexaferrite as the magnetic particles (col. 1, lines 37-39).

Regarding the form of the composition (claims 5 and 6), Maor et al teach that the compositions are cream /emulsion compositions including milk, lotion, cream, and ointment (page 2). Zastrow '988 teach that the compositions are in emulsion, cream, and ointment form (see Examples 1, 2, and 4).

Regarding claim 8, Maor et al teach that odorants such as fragrance may be present (Table 1, page 6), Zastrow '988 teach that cosmetic active ingredients, such as vitamins, may be present (col. 3, lines 13-16).

Regarding claims 11 and 12, Zastrow '988 teach that the magnetic particles have a particle size in the range of 80 to 550 nm. This would, therefore, classify them as "nanoparticles". Furthermore, the size range cited in Zastrow '988 overlaps with the size range described in claims 11 and 12 of the claimed invention, and one skilled in the art would have be motivated to select an optimal size for the magnetic particles from within said ranges by routine experimentation, in order to optimize the wound healing and anti-inflammatory properties of the magnetic particles.

Regarding claims 16 and 17, Zastrow '988 teach strontium hexaferrite as the magnetic particles (col. 1, lines 37-39) in an amount from 0.001 to 50 wt% (col. 1, lines 62-63). This amount range overlaps that of the claimed invention, i.e., 400 ppm (or 0.04%); one skilled in the art would be motivated to manipulate the amount of strontium hexaferrite from within said ranges by routine experimentation, in order to optimize the wound healing and anti-inflammatory properties of the magnetic particles.

Response to Arguments

10. Applicant's arguments filed 1/22/09 have been fully considered but they are not persuasive.

Applicants argue that Zastrow '988 does not attribute the (wound healing) effect to magnetic particles alone but rather to their use in combination with asymmetrical lamellar aggregates which are completely loaded with oxygen. Applicants assert that one skilled in the art would recognize Zastrow '988 as teaching away from the use of magnetic particles, because Zastrow '988 does not provide a teaching as to the efficacy in using magnetic particles in the absence of the lamellar aggregates. Applicants further argue that, if Zastrow '988 or Maor were considered as the closest prior art, a combination with the other reference would not have arisen to the claimed invention because the preparation would necessitate also the inclusion of lamellar aggregates.

This argument is not persuasive. The claimed invention allows for the presence of the asymmetrical lamellar aggregates taught in Zastrow '988, due to the use of the open-ended term "comprising". Further, Applicants have not provided any evidence or

reasoning as to why the presence of the asymmetrical lamellar aggregates taught in Zastrow '988 would prevent the combination of its preparation containing the magnetic particles with the Dead Sea mud of Maor. Therefore, the combination of Maor with Zastrow '988 (further in view of Shiga Yoko) renders the claimed invention *prima facie* obvious.

Applicants also argue that the particles of Zastrow '988 have a coercive field strength of 1,000 to 20,000 Oerstedt, while the nanoparticle in currently amended claim 1 of the claimed invention are demagnetized nanoparticles, which are suitable for magnetization when dispersed in the preparation or when applied onto the skin of a subject.

This argument has been considered but is deemed moot in light of the grounds of rejection now being further in view of Shiga Yoko.

Applicants also argue that a person skilled in the art would not have had the incentive to reduce the magnetic particle size, and would recognize Zastrow '988 as teaching away from such action, citing col. 2, lines 6-22 of Zastrow '988.

This argument is not persuasive because the teachings of Zastrow '988 cited by Applicants state that, as the particle size was reduced, the efficacy was actually increased (see lines 16-17). Therefore, one skilled in the art would, in fact, be motivated to combine the composition of Zastrow '988 with the composition of Maor.

Applicants state that they believe the Examiner's objection to the Declaration filed 6/19/08 is rendered "mute" in view of the arguments provided. However, as Applicant's arguments are not persuasive for overcoming the rejection, the Declaration

is still not persuasive for overcoming the rejection, for reasons of record. To reiterate from the previous Office action of 9/25/08, the Declaration is not persuasive because the results obtained from the combination of DerMud and strontium hexaferrite versus DerMud alone would not be unexpected. Since DerMud is known to provide relief for skin diseases and disorders (see abstract of Maor et al), and strontium hexaferrite is known to have a wound healing effect and be useful for treating hypersensitive skin (see Example 2 of Zastrow et al), the skilled artisan would reasonably expect that the combination of DerMud and strontium hexaferrite would show greater efficacy than either component by itself. Therefore, the Declaration merely illustrates what would reasonably be expected by one skilled in the art at the time the invention was made, and does not represent a patentable distinction or improvement over the prior art.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
April 8, 2009